109TH CONGRESS
1ST SESSION

S. 1880

To amend the Public Health Service Act to enhance biodefense and pandemic preparedness activities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2005

Mr. KENNEDY (for himself, Mr. DODD, Mr. HARKIN, Ms. MIKULSKI, Mr. BINGAMAN, Mrs. CLINTON, Mr. SCHUMER, and Mr. OBAMA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to enhance biodefense and pandemic preparedness activities, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''National Biodefense and Pandemic Preparedness Act of 2005''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—RESTRUCTURING THE NATIONAL BIODEFENSE INITIATIVE

SEC. 101. NATIONAL BIODEFENSE TRUST.

(a) NATIONAL BIOVENTURE TRUST.—

(1) PURPOSE.—It is the purpose of this subsection to establish a Federal Government corporation for the purpose of—

(A) administering the Federal BioShield program; and

(B) identifying and supporting the development of promising technologies that could lead to the development of qualified countermeasures.

(2) ESTABLISHMENT OF TRUST.—There is established a body corporate to be known as the ''National BioVenture Trust'' (referred to in this section as the ''Trust'') which shall be in the Department of Health and Human Services. The Trust shall have succession until dissolved by Act of Congress. It shall maintain its principal office in the District of Columbia and shall be deemed, for purposes of venue in civil actions, to be a resident thereof. Agencies or offices may be established by the Trust in such other place or places as it may deem necessary or appropriate in the conduct of its business.

(3) CAPITALIZATION.—The Trust shall have common stock, without par value, which shall be vested with all voting rights, each share being entitled to one vote with rights of cumulative voting at all elections of directors. The Trust may eliminate such rights of cumulative voting by a resolution adopted by its board of directors and approved by the holders of a majority of the shares of common stock voting in person or by proxy at the annual

meeting, or other special meeting, at which such resolution is considered. The corporation may have preferred stock on such terms and conditions as the board of directors shall prescribe. The free transferability of the stock at all times to any person, firm, corporation, or other entity shall not be restricted except that, as to the Trust, it shall be transferable only on the books of the Trust. The Trust may issue shares of common stock in return for appropriate payments into capital or capital and surplus. Any proceeds derived by the Trust under this paragraph shall be reinvested for the develop of new technology. Notwithstanding any other provision of law, the Secretary of Health and Human Service shall ensure that not less than 51 percent of the stock provided for under this paragraph s held by the Department of Health and Human Services.

(4) GENERAL MANAGEMENT.—There is hereby established in the Department of Health and Human Services the position of Chief Executive Officer, National BioVenture Trust, who shall be appointed by the President in consultation with the Secretary, subject to the advice and consent of the Senate. All the powers and duties of the Trust shall be vested in the Chief Executive Officer. The Sec-

retary shall select and effect the appointment of qualified persons to fill the offices of vice president, and such other offices as may be provided for in the bylaws of the Trust. Persons appointed under the preceding sentence shall perform such executive functions, powers, and duties as may be prescribed by the bylaws or by the Secretary, and such persons shall be executive officers of the Trust and shall discharge all such executive functions, powers, and duties. The Chief Executive Officer may participate in meeting provided for under section 2(g) of the Clayton Act (15 U.S.C. 13) (as added by section 103 of this Act). In carrying out the activities under this subsection, the Chief Executive Officer, in consultation with the National Advisory Committee on Vulnerable Populations and Terrorism, and the Vulnerable Populations Working Group, and based on the recommendations of the Secretary, shall give priority to supporting and facilitating research and development of countermeasures, and formulations of countermeasures, that are likely to be safe and effective for pediatric populations, pregnant women, and other vulnerable populations.

(5) BOARD OF DIRECTORS.—

(A) IN GENERAL.—The Trust shall have a board of directors, which shall consist of 18 individuals, 9 of whom shall be appointed annually by the Secretary, and the remainder of whom shall be elected annually by the common stockholders. The board shall at all times have as members appointed by the Secretary at least 3 individuals from the biotechnology or pharmacology industry, at least 3 individuals with experience in chemical, nuclear, or biological threats to the United States (including naturally occurring biological threats), and at least 3 individuals who are representatives of healthcare consumers or workers.

(B) TERMS AND VACANCIES.—Each member of the board of directors shall be appointed or elected for a term ending on the date of the next annual meeting of the stockholders, except that any such appointed member may be removed from office by the Secretary for good cause. Any elective seat on the board which becomes vacant after the annual election of the directors shall be filled by the board, but only for the unexpired portion of the term. Any appointive seat which becomes vacant shall be

filled by appointment of the Secretary, but only for the unexpired portion of the term.

(C) POWERS.—Within the limitations of law and regulation, the board shall determine the general policies which shall govern the operations of the Trust, and shall have power to adopt, amend, and repeal bylaws governing the performance of the powers and duties granted to or imposed upon it by law. The board of directors shall select and effect the appointment of qualified persons to fill the offices of president and vice president, and such other offices as may be provided for in the bylaws. The board shall make recommendations to the Chief Executive Officer concerning the policies for administering the Trust.

(D) COMPENSATION.—Any member of the board who is a full-time officer or employee of the Federal Government shall not, as such member, receive compensation for his or her services.

(6) GRANTS.—

(A) IN GENERAL.—The Trust shall award grants to entities that have developed technologies that may (as determined by the Trust)

lead to the development of qualified countermeasures. The Trust shall ensure that grant funds are not provided under this section for activities that will substantially occur outside of the United States.

(B) POLICIES.—The Trust shall develop policies and procedures for the awarding of grants under subparagraph (A).

(C) REASONABLE PRICING.—To be eligible to receive a grant under subparagraph (A), an entity shall enter into an agreement with the Trust under which—

(i) products developed using grant funds will be made available at reasonable prices to the Trust, the Federal Government, and other consumers, except that in lieu of such an agreement, a grantee may provide the Trust with equity in return for the receipt of grant funds;

(ii) product developed using grant funds will be made available as provided for under clause (i) at not more than the market share price that exists on the commercial market; and

(iii) the Trust is provided with the authority to sell equity in products developed using grant funds and obtained by the Trust and to apply the proceeds from such sales for the awarding f grants under subparagraph (A).

(7) MISCELLANEOUS PROVISIONS.—

(A) IN GENERAL.—The Trust shall have power to—

(i) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(ii) to enter into and perform contracts, leases, cooperative agreements, or other transactions, on such terms as it may deem appropriate, with any agency or instrumentality of the United States, or with any State, Territory, or possession, or the Commonwealth of Puerto Rico, or with any political subdivision thereof, or with any person, firm, association, or corporation; to execute, in accordance with its bylaws, all instruments necessary or appropriate in the exercise of any of its powers;

(iii) in its corporate name, to sue and to be sued, and to complain and to defend,

in any court of competent jurisdiction, State or Federal, but no attachment, injunction, or other similar process, final, shall be issued against the property of the Trust or against the Trust with respect to its property;

(iv) to conduct its business without regard to any qualification or similar statute in any State of the United States, including the District of Columbia, the Commonwealth of Puerto Rico, and the Territories and possessions of the United States;

(v) to lease, purchase, or acquire any property, real, personal, or mixed, or any interest therein, to hold, rent, maintain, modernize, use, and operate such property, and to sell, for cash or credit, lease, or otherwise dispose of the same, at such time and in such manner as and to the extent that it may deem necessary or appropriate;

(vi) to prescribe, repeal, and amend or modify, rules, regulations, or requirements governing the manner in which its general business may be conducted; and

(vii) to do all things as are necessary or incidental to the proper management of its affairs and the proper conduct of its business.

(B) DETERMINATION WITH RESPECT TO OBLIGATIONS AND EXPENDITURES.—Except as may be otherwise provided in this section, with respect to chapter 91 of title 31, or in other laws specifically applicable to Government corporations, the Trust shall determine the necessity for and the character and amount of its obligations and expenditures and the manner in which they shall be incurred, allowed, paid, and accounted for.

(C) EXEMPTION FROM TAXATION.—The Trust, including its franchise, capital, reserves, surplus, security holdings, and income shall be exempt from all taxation now or hereafter imposed by the United States, by any territory, dependency, or possession thereof, or by any State, county, municipality, or local taxing authority, except that any real property of the Trust shall be subject to State, territorial, county, municipal, or local taxation to the same

extent according to its value as other real property is taxed.

(D) APPOINTMENT AND COMPENSATION OF PERSONNEL; USE OF SERVICES OF OTHER AGENCIES.—

(i) APPOINTMENT AND COMPENSATION.—The Secretary shall have to power to select and appoint or employ such officers, attorneys, employees, and agents of the Trust, to vest them with such powers and duties, and to fix and to cause the Trust to pay such compensation to them for their services, as he may determine, subject to the civil service and classification laws.

(ii) USE OF AGENCIES.—With the consent of any Government corporation, or of any board, commission, independent establishment, or executive department of the Government, the Trust may avail itself on a reimbursable basis of the use of information, services, facilities, officers, and employees thereof, including any field service thereof, in carrying out the provisions of the section.

(iii) COMPENSATION.—The board of directors of the Trust shall have the power to select and appoint or employ such officers, attorneys, employees, and agents, to vest them with such powers and duties, and to fix and to cause the Trust to pay such compensation to them for their services, as the board of directors determines reasonable and comparable with compensation for employment in other similar businesses involving similar duties and responsibilities, except that a significant portion of potential compensation of all executive officers of the Trust shall be based on the performance of the Trust, and any such action shall be without regard to the Federal civil service and classification laws. Appointments, promotions, and separations so made shall be based on merit and efficiency, and no political tests or qualifications shall be permitted or given consideration.

(E) PROHIBITION AGAINST USE OF NAMES; INJUNCTION; DAMAGES.—No individual, association, partnership, or corporation, except the

Trust shall use the words ''National BioVenture Trust'' as the name under which the individual, association, partnership, or corporation shall do business. Violations of the foregoing sentence may be enjoined by any court of general jurisdiction at the suit of the proper body corporate. In any such suit, the plaintiff may recover any actual damages flowing from such violation, and, in addition, shall be entitled to punitive damages (regardless of the existence or non-existence of actual damages) of not exceeding $100 for each day during which such violation is committed or repeated.

(F) VULNERABLE POPULATIONS WORKING GROUP.—The Trust shall establish and convene a Vulnerable Populations Working Group composed of experts on pediatric populations, pregnant women, and other vulnerable populations to advise the Trust with respect to—

(i) supporting and facilitating research and development of countermeasures, and formulations of countermeasures, that are safe and effective for such populations; and

(ii) other activities of the Trust that effect such populations.

(b) STUDY.—Not later than 120 days after the date of enactment of this Act, the Government Accountability Office shall conduct a study, and submit to the appropriate committees of Congress, a report on the efficient organization of the administrative structure of the Federal Government for responding to public health emergencies. Such report shall contain the specific recommendations of the Government Accountability Office on—

(1) whether the Assistant Secretary for Health of the Department of Health and Human Services and the Surgeon General positions should be held by same individual; and

(2) the manner in which to improve coordination between the Assistant Secretary for Health, the Surgeon General, the National Institutes of Health, and the Centers for Disease Control and Prevention with respect to biodefense preparedness.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriate to carry out this section, $1,000,000,000 for fiscal year 2006, and such sums as may be necessary for each subsequent fiscal year.

(d) CONFORMING AMENDMENTS.—Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)) is amended—

(1) in paragraph (3), by striking ''Secretary, in consultation with the Homeland Security Secretary,'' and inserting ''National BioVenture Trust (referred to in this section as the 'Trust')'';

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) by striking ''Homeland Security Secretary and the Secretary make'' and inserting ''Trust makes''; and

(ii) by striking ''such Secretaries may jointly submit to the President a proposal to'' and inserting ''the Trust may'';

(B) in subparagraph (B), by striking ''Homeland Security Secretary and the Secretary'' and inserting ''Trust''; and

(C) by striking subparagraph (C);

(3) in paragraph (5)—

(A) in subparagraph (A)—

(i) by striking ''The Secretary'' and inserting ''The Trust''; and

(ii) by striking ''Secretary determines, in consultation with the Homeland Secu-

rity Secretary,'' and inserting ''Trust determines''; and

(B) in subparagraph (B), by striking ''Secretary'' and inserting ''Trust'';

(4) in paragraph (6)—

(A) by striking subparagraphs (A) and (B);

(B) in subparagraph (C), by striking ''Secretary and the Homeland Security Secretary'' and inserting ''Trust''; and

(C) by redesignating subparagraphs (C) through (E), as subparagraphs (A) through (C), respectively;

(5) in paragraph (7)—

(A) in subparagraph (B), by striking ''the Secretary'' each place that such appears and inserting ''the Trust''; and

(B) in subparagraph (C)—

(i) by striking ''the Secretary'' each place that such appears and inserting ''the Trust'';

(ii) in clause (i), by striking ''The Secretary'' and inserting ''The Trust'';

(iii) in clause (ii)—

(I) in subclause (I), by striking ''The Secretary's'' and inserting ''The Trust's''; and

(II) by adding at the end the following:

''(VII) DELIVERY TO SECRETARY.—The contract shall provide that the products that are the subject of the contract shall be delivered to the Secretary (subject to the provisions of subclause (IV)) for inclusion in the National Strategic Stockpile.'';

(iv) in clause (iii), by striking ''the Secretary'' each place that such appears and inserting ''the Trust'';

(v) in clause (iv), by striking ''the Secretary'' each place that such appears and inserting ''the Trust'';

(vi) in clause (v)—

(I) by striking ''the Secretary'' each place that such appears and inserting ''the Trust''; and

(II) in subclause (II), by striking ''The Secretary's'' and inserting ''The Trust's'';

(vii) in clause (vi), by striking ''The Secretary'' and inserting ''The Trust''; and

(viii) in clause (vii), by striking ''The Secretary'' and inserting ''The Trust'';

(6) by striking paragraph (8); and

(7) by redesignating paragraphs (9) and (10) as paragraphs (8) and (9), respectively.

SEC. 102. STRATEGIC BIODEFENSE INITIATIVE.

(a) CALL FOR THE DEVELOPMENT OF COUNTERMEASURES.—Section 319F–2(c)(4) of the Public Health Service Act (as added by Public Law 108–276) is amended by adding at the end the following:

''(D) STATEMENT OF INTENT.—

''(i) IN GENERAL.—On any date that is subsequent to the date on which the Trust issues under subparagraph (B) a call for the development of a countermeasure, a person planning to develop the countermeasure that is the subject of such call may file with the Trust a statement of intent to develop such countermeasure.

''(ii) CONTENTS.—A statement of intent under clause (i) shall include a plan for the development of the countermeasure

that is the subject of the call approved under subparagraph (C).

''(iii) ADVANCE PAYMENT.—The Trust may make an advance payment described in paragraph (7)(C)(ii)(I) only to a person that has submitted a statement of intent under this subparagraph.

''(E) EVALUATION OF STATEMENT OF INTENT.—

''(i) NO FILING OF QUALIFIED STATEMENT.—If, by the date that is 120 days after the date on which the Trust issues a call for the development of a security countermeasure under subparagraph (B) (and subject to an extension of such period under clause (iii)), the Trust finds that no person has filed a statement of intent under subparagraph (D) that includes a plan for the development of such countermeasure that, in the determination of the Trust, is likely to lead to the development of such countermeasure in a manner that—

"(I) meets the specifications described under subparagraph (B) with respect to the countermeasure; and

"(II) satisfies the requirement of paragraph (5)(B)(ii);

then the Trust shall make the declaration of non-response described in subsection (d).

"(ii) EXTENSION OF TIME PERIOD—.—The 120-day period described in clause (i) shall be extended in the case of a grant awarded under subparagraph (F) for the duration of the grant period.".

(b) ESTABLISHMENT OF INITIATIVE.—Section 319F–2 of the Public Health Service Act (as added by Public Law 108–276) is amended—

(1) by redesignating subsections (d) through (f), as subsections (e) through (g), respectively; and

(2) by inserting after subsection (c), the following:

"(d) STRATEGIC BIODEFENSE INITIATIVE.—

"(1) DECLARATION OF NON-RESPONSE.—If the Trust makes the finding described in subsection (c)(4)(E)(i), the Trust shall declare and communicate promptly to the Secretary that no person has

responded adequately to the call for the development of a security countermeasure under subsection (c)(4). Such declaration shall specify the security countermeasure with respect to which the declaration applies.

''(2) REQUIREMENT FOR FEASIBILITY DETERMINATION.—

''(A) DETERMINATION OF FEASIBILITY.—If the Trust makes a declaration described in paragraph (1) with respect to a security countermeasure, the Secretary shall determine whether it is feasible to produce the countermeasure at reasonable cost and within a reasonable time through the procedures described in paragraph (3).

''(B) FURTHER REVIEW REQUIRED.—If the Secretary makes a negative determination under subparagraph (A), the Secretary shall determine whether it is feasible to produce such countermeasure at reasonable cost and within a reasonable period of time through the procedures described in paragraph (4).

''(3) PRODUCTION OF COUNTERMEASURES THROUGH CONTRACT.—

"(A) IN GENERAL.—This paragraph shall apply only if the Secretary has made a positive determination under paragraph (2)(A).

"(B) DEVELOPMENT OF PLAN.—Not later than 120 days after making a positive determination under paragraph (2)(A), the Secretary shall develop a plan for the production of the countermeasure involved through the procedures described in subparagraph (C).

"(C) OFFERS OF CONTRACT.—Following the development of the plan under subparagraph (B), the Secretary shall issue an offer to enter into contracts with any person for research, development, testing, production, or any other activity that, in the determination of the Secretary, is likely to expedite the implementation of the plan under such subparagraph.

"(D) TERMS OF OFFER.—The offer described in subparagraph (C) shall describe the service or other activity for which the Secretary desires to enter into the contract and shall include a description of the terms of the contract as specified in subparagraph (E).

''(E) TERMS OF CONTRACT.—A contract entered into pursuant to an offer under subparagraph (C) shall provide that—

''(i) the Secretary will retain the intellectual property rights to any product developed under the contract;

''(ii) the Secretary will own the product developed under the contract;

''(iii) the product developed under the contract will become a part of the national stockpile under subsection (a); and

''(iv) the terms described in subsection (c)(7)(C)(ii) shall apply.

''(F) SATISFACTORY BIDS NOT RECEIVED.—If, within 120 days of the issuance of an offer described in subparagraph (C), the Secretary has not received a bid or bids from any person or persons to enter into a contract or contracts for the services or other activities described in such offer that, in the determination of the Secretary, will result in the production of the specified countermeasure at reasonable cost and within a reasonable time, the Secretary shall issue a statement indicating that satisfactory bids have not been received and

shall conduct the feasibility determination described in paragraph (2)(B).

''(4) PRODUCTION OF COUNTERMEASURES BY THE SECRETARY.—

''(A) IN GENERAL.—This paragraph shall apply only if the Secretary has made a positive determination under paragraph (2)(B) or if the Secretary has issued a statement under paragraph (3)(F).

''(B) PLAN REQUIRED.—Not later than 120 days after making a positive determination under paragraph (2)(B) or issuing a statement under paragraph (3)(F), the Secretary shall develop a plan for producing the countermeasure involved.

''(C) PRODUCTION OF COUNTERMEASURES.—Following the development of the plan under subparagraph (B), the Secretary shall conduct activities, subject to the availability of funds under paragraph (8), necessary to implement the plan under subparagraph (B). Such activities may include the production of countermeasures at facilities owned or operated by the Secretary or the expansion, enhancement or improvement of such facilities.

''(5) APPLICATION OF PROVISIONS.—The provisions of clauses (iii) through (vii) of subsection (c)(7)(C) shall apply to the procurement of countermeasures under contracts under this subsection. The provisions of section 319F–1(f) shall apply to actions of the Secretary under paragraphs (1) through (4).

''(6) GUIDELINES.—The Secretary, pursuant to existing authority with respect to contracts with private sector entities, shall establish guidelines concerning the process of entering into contracts under this subsection, including the submission and review of bids by entities.

''(7) FUNDING.—

''(A) IN GENERAL.—To carry out this subsection, the Secretary may use not to exceed 10 percent of the amounts in the special reserve fund under subsection (c)(10) in each fiscal year.

''(B) AUTHORIZATION.—In addition to the amounts described in subparagraph (A), there are authorized to be appropriated such additional funds as may be necessary for each of fiscal years 2005 through 2009 to carry out this subsection.''.

SEC. 103. COLLABORATION AND COORDINATION.

(a) IN GENERAL.—Section 2 of the Clayton Act (15 U.S.C. 13) is amended by adding at the end the following:

''(g) LIMITED ANTITRUST EXEMPTION.—

''(1) QUALIFIED COUNTERMEASURES AND QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DEVELOPMENT MEETINGS.—

''(A) COUNTERMEASURES AND PRODUCTS DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') or the Chief Executive Officer of the National BioVenture Trust (referred to in this subsection as the 'CEO'), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with parties involved in the development of qualified countermeasures (as defined in section 319F–2 of the Public Health Service Act) or qualified pandemic or epidemic products (as defined in section 319F–3(c)(5) of the Public Health Service Act) (referred to in this section as ''countermeasures or products'') for the purpose of the development, manufacture, distribution, purchase, sale, or storage of countermeasures or products consistent with

the purposes of this title. The Secretary or CEO may convene such meeting or consultation at the request of any person, the Secretary of Homeland Security, the Attorney General, the Chairperson of the Federal Trade Commission, an industry representative or member, or upon initiation by such Secretary. The Secretary or CEO shall give notice of such meetings and consultations to the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

''(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

''(i) be chaired or, in the case of a consultation, facilitated by the Secretary or CEO;

''(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of countermeasures or products, as determined by the Secretary or CEO;

''(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairperson;

"(iv) be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures or products, consistent with the purposes of this title; and

"(v) be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation.

"(C) LIMITATION.—The Secretary or CEO may not require the disclosure of confidential commercial or proprietary information.

"(D) MINUTES.—The Secretary or CEO shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code, unless such Secretary or CEO, in consultation with the Attorney General, determines that disclosure would pose no threat to national security. Such determination shall not be subject to judicial review.

"(E) EXEMPTION.—

"(i) IN GENERAL.—The antitrust laws shall not apply to meetings and consultations under this paragraph.

''(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection.

''(2) WRITTEN AGREEMENTS.—The Secretary or the CEO shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing shall include—

''(A) an explanation of the intended purpose of the agreement;

''(B) a specific statement of the substance of the agreement;

''(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

''(D) an explanation of the necessity of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

''(E) any other relevant information determined necessary by the Secretary or CEO in consultation with the Attorney General and the Chairperson.

''(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement regarding covered activities referred to in paragraph (2) would likely—

''(A) be in compliance with the antitrust laws, and so inform the Secretary or CEO and the participating parties; or

''(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement consistent with the purposes of this title.

''(4) ACTION ON REQUEST FOR EXEMPTION.—

''(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 days of the receipt of such request.

''(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 days. Such additional period may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary or CEO and the parties involved.

''(C) DETERMINATION.—The Attorney General, in consultation with the Chairperson and the Secretary or CEO—

''(i) may not grant an exemption under this paragraph unless the Attorney General finds—

''(I) that the agreement involved is necessary to ensure the availability of countermeasures or products;

''(II) that the exemption from the antitrust laws would promote the public interest; and

''(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

"(ii) may consider any other factors determined relevant by the Attorney General or the Chairperson.

"(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and shall be renewed (with modifications, as appropriate) on the date that is 3 years after the date on which the exemption becomes effective (and at 3-year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

"(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

"(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

''(8) REPORT.—Not later than 1 year after the date of enactment of this subsection, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

''(9) STATUS OF MEMORANDUMS.—Minutes maintained by the Secretary or CEO pursuant to paragraph (1)(D) shall not be disclosed under section 552 of title 5, United States Code, if the exemption is not renewed under paragraph (5), or if meetings are no longer conducted, unless the Secretary or CEO, in consultation with the Attorney General, determines that the disclosure would pose no threat to national security. Such determination shall not be subject to judicial review.

''(h) DEFINITIONS.—In this section:

''(1) ANTITRUST LAWS.—The term 'antitrust laws'—

''(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) commonly known as the Robinson-Patman Act), and section 5 of the Federal

Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

"(B) includes any State law similar to the laws referred to in subparagraph (A).

"(2) COVERED ACTIVITIES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

"(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of countermeasures or products;

"(ii) the development or testing of basic engineering techniques necessary to the development of countermeasures or products;

"(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes,

including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of countermeasures or products;

''(iv) the production, distribution, or marketing of a product, process, or service that is a countermeasures or products;

''(v) the testing in connection with the production of a product, process, or services necessary to the development of countermeasures or products;

''(vi) the collection, exchange, and analysis of research or production information necessary to the development of countermeasures or products; or

''(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and

the granting of licenses for the results of such covered activities.

''(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

''(i) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service if such information is not reasonably necessary to carry out the purposes of covered activities.

''(ii) Entering into any agreement or engaging in any other conduct—

''(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

''(II) to restrict or require participation by any person who is a party to such covered activities in other research and development activi-

ties, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

''(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws by a determination under subsection (g)(4).

''(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out the purpose of such covered activities.

''(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not so expressly exempted from the

antitrust laws by a determination under subsection (g)(4).

''(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

''(4) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure or products.''.

(b) TERMINATION OF AUTHORITY.—The authority provided for in the amendment made by subsection (a) shall terminate on the date that is 5 years after the date of enactment of this Act.

(c) REPORT.—Not later than 4 years after the date of enactment of this Act, the Government Accountability Office shall submit to the appropriate committees of Congress a report on the activities conducted under the au-

thority provided under the amendment made by subsection (a).

TITLE II—ENSURING NATIONAL VACCINE MANUFACTURING CAPACITY

SEC. 201. WARM-BASED MANUFACTURING FOR BIOLOGICAL COUNTERMEASURES.

Section 319F–2(c)(7)(C)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended by section 101(d), is further amended by adding at the end the following:

''(VIII) WARM-BASED MANUFACTURING.—The contract shall, if the product is a biological product, provide for annual payments after the initial delivery of the product to meet the needs of the stockpile to pay the cost of maintaining domestic manufacturing capacity for, and providing additional units of, the product to the stockpile sufficient to allow the Secretary in an emergency or other time of need to promptly acquire additional units of the product for the stockpile.''.

SEC. 202. EMERGENCY MANUFACTURING.

Section 319F–2(c)(7)(C)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended by section 201, is further amended by adding at the end the following:

> ''(IX) EMERGENCY MANUFACTURING.—The contract shall, if the product is not a biological product, provide for domestic manufacturing capacity, including through alternate domestic manufacturing arrangements such as through licensing to another manufacturer and preapproval of such manufacturer's product by the Food and Drug Administration, sufficient to allow the Trust in an emergency or other time of need to promptly acquire additional units of the product for the stockpile. Such contract shall ensure that the intellectual property resulting from such contract become the property of the Federal Government.''.

SEC. 203. CONSTRUCTION OF FACILITIES.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by adding at the end the following:

''(k) LOANS FOR CONSTRUCTION.—

''(1) IN GENERAL.—The Secretary shall establish a program under which the Secretary may make loans to eligible entities to enable such entities to provide for the construction of countermeasure manufacturing facilities.

''(2) ELIGIBILITY.—To be eligible to receive a loan under paragraph (1), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

''(3) FORGIVENESS OF LOAN AMOUNTS.—The Secretary may forgive up to 25 percent of the amount of a loan if the entity involved enters into an agreement with the Secretary to permit the facilities constructed using loan amounts to be made available to produce any countermeasure product specified by the Secretary upon the declaration of a public health emergency under section 319.

''(4) LABOR STANDARDS.—All laborers and mechanics employed by contractors or subcontractors on projects assisted by the Secretary of Health and

Human Services under this Act (or an amendment made by this Act) shall be paid wages at rates not less than those prevailing on similar construction in the locality involved, as determined by the Secretary of Labor, in accordance with sections 3141 through 3144, 3146, and 3147 of title 40, United States Code. The Secretary of Health and Human Services shall not award any contract, grant, cooperative agreement, or other transaction under this Act (or amendments) for such a project without first obtaining adequate assurance that the labor standards provided for in this subsection will be maintained upon the construction project. The Secretary of Labor shall have, with respect to the labor standards specified in this subsection, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 64 Stat. 1267), and section 3145 of title 40, United States Code.

''(5) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this section.''.

TITLE III—IMPROVING PROJECT BIOSHIELD

SEC. 301. IMPROVING PROJECT BIOSHIELD.

(a) STATEMENT OF CONGRESSIONAL INTENT.—Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)) is amended—

(1) by redesignating paragraphs (1) through (9) as paragraphs (2) through (10), respectively; and

(2) by inserting before paragraph (2), as so redesignated, the following:

''(1) STATEMENT OF CONGRESSIONAL INTENT.—

''(A) IN GENERAL.—The intent of Congress in establishing Project BioShield (under the Project BioShield Act of 2004 (Public law 108–276)) is—

''(i) that the Project provide a guaranteed market for products for which the incentives of the commercial market are inadequate to induce their development and which meet important national needs in preparing for material threats to the health of the American public;

''(ii) that the Project is not intended simply to procure products that are in advanced stages of development; and

''(iii) that the Project should identify national needs in preparing for material threats to the health of the American public and accelerate the development of countermeasures to meet those needs.

''(B) REQUIREMENT TO FOLLOW INTENT.—Activities conducted under this subsection shall be consistent with the statement of intent described in subparagraph (A).''.

(b) AMENDMENTS.—Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)), as amended by subsection (a), is further amended—

(1) in paragraph (2)(B)—

(A) in clause (i)—

(i) in subclause (I), by striking ''(consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002)'';

(ii) in subclause (III)(bb), by striking ''within eight years'' and inserting ''within 8 years or such additional time as the Trust determines to be reasonable''; and

(iii) by striking ''or'' at the end thereof;

(B) in clause (ii), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) is a vaccine or microbicide used to treat or prevent AIDS, tuberculosis, Malaria, or a strain of influenza that may (in the determination of the Secretary) contribute to a pandemic.'';

(2) in paragraph (3)—

(A) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively;

(B) by inserting after subparagraph (B), the following:

''(C) REQUESTS FOR DETERMINATIONS.—The Secretary may request the Homeland Security Secretary to make a determination with respect to a specific chemical, biological, radiological, or nuclear agent. The Homeland Security Secretary shall respond to such request within 90 days of such request.''; and

(C) in subparagraph (D) (as so redesignated), by striking ''or (B)'' and inserting '', (B), or (C)''; and

(3) in paragraph (6)(B)—

(A) in clause (ii), by striking ''within eight years'' and inserting ''within 8 years or such additional time as the Trust determines to be reasonable''; and

(B) by striking clause (iii) and inserting the following:

''(iii) Whether the commercial market for the product is sufficient to ensure the continued development of the product. If the determination under this clause is that the commercial market for the product is sufficient, funds available under this subsection may not be provided for such product.''.

TITLE IV—INCENTIVES FOR COUNTERMEASURE DEVELOPMENT

SEC. 401. PRIZE PAYMENTS FOR COUNTERMEASURES DEVELOPMENT.

Section 319F–2(f) of the Public Health Service Act (42 U.S.C. 247d–6b(f)) is amended by adding at the end the following:

''(3) PRIZE PAYMENT FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.—

''(A) IN GENERAL.—If the Secretary determines that it is necessary to engage a biotechnology or pharmaceutical company to ensure the development and production of a countermeasure, and that procurement under subsection (c)(7) will not engage such a company, the Secretary may recommend that the President request that Congress appropriate a prize payment, in a sum that shall not exceed $1,000,000,000, to be made to such company upon the delivery of the total number of units of the countermeasure contracted for.

''(B) REQUIREMENTS.—If the Secretary makes a recommendation under subparagraph (A), the President shall promptly—

"(i) request that Congress appropriate such a sum for a prize payment for such countermeasure; or

"(ii) report to Congress concerning why such recommendation is inappropriate.

"(C) REASONABLE PRICING.—To be eligible to receive a payment under this paragraph, a manufacturer shall provide assurances that the countermeasure with respect to which the payment is to be made will be made available—

"(i) to the Federal Government at the lowest of —

"(I) the price paid for that product by the Department of Veterans Affairs;

"(II) the Federal ceiling price; or

"(III) the Federal supply schedule price; and

"(ii) to the general public at a reasonable price determined by the Secretary through negotiations with the recipient, but in no case shall such price be higher than the average price paid for the countermeasure in the G–8 nations.

''(D) LICENSE.—To be eligible to receive a payment under this paragraph, a manufacturer shall provide assurances that a license for the countermeasure with respect to which the payment is to be made will be made shall be granted to produce the product at low cost in the developing world (as determined by the Secretary).

''(E) PREFERENCE.—In making payments under this paragraph, the Secretary shall give preference to any vaccine or microbicide for AIDS, Tuberculosis, malaria, or a strain of influenza that (in the determination of the Secretary) contribute to a pandemic that is likely to significantly reduce global mortality from these diseases.

''(F) FUNDING.—

''(i) AUTHORIZATION OF APPROPRIATIONS.—For purposes of this paragraph, there are authorized to be appropriated $3,000,000,000 for fiscal year 2006, and such sums as may be necessary in each fiscal year thereafter, to be used as a prize payment to be made to the vendor involved in the fiscal year in which the vendor deliv-

ers the total number of units contracted for. Amounts appropriated under this subparagraph shall remain available until expended.

''(ii) ACCEPTANCE OF DONATIONS.—Notwithstanding any other provision of law, the Secretary may accept donations from foreign governments and other entities for the purpose of awarding prizes under this paragraph. The Secretary may use amounts received under this clause to increase the amount of prizes under this paragraph.''.

SEC. 402. PROVIDING FOR LONG-TERM SOLE-SOURCING OF COUNTERMEASURES.

Section 319F–2(c)(8)(C)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended by section 202, is further amended by adding at the end the following:

''(X) SOLE SOURCING.—

''(aa) IN GENERAL.—The contract shall provide that the vendor shall be the sole source for the countermeasure for the stockpile under subsection (a) for

a period of 20 years from the first date of delivery of the product to the Secretary under the contract, except that the contract shall provide that the Secretary may purchase the countermeasure from another source to the extent to which the vendor is unable or unwilling to deliver the product in the quantity or timeframe required by the Secretary or if the vendor permits purchase from another source.

''(bb) RULE OF CONSTRUCTION.—Nothing in item (aa) shall be construed to prevent the Secretary from purchasing a countermeasure from a source other than the source described in such item.''.

TITLE V—CROSSING THE VALLEY OF DEATH

SEC. 501. EARLY SUPPORT FOR COUNTERMEASURE DEVELOPMENT.

Section 319F–2(c)(4) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(4)), as amended by section 102, is further amended by adding at the end the following:

''(F) SUPPORT FOR CALL FOR COUNTERMEASURE.—The Secretary may provide grants to one or more of the persons to whom a call for a countermeasure is made known under subparagraph (C) to support the cost of screening, research, development, testing, and initial manufacture of potential candidates for such countermeasure.''.

SEC. 502. INCENTIVE PAYMENTS.

Section 319F–2(c)(7)(C)(ii)(I) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)(I)) is amended by adding at the end the following: ''In addition to the advance payments described in the preceding sentences, the contract may provide for not more than 3 incentive payments to be made, each in an amount that does not exceed 5 percent of the contract amount, for the achievement by the manufacturer of specific milestones. Any such

incentive payments shall not be required to be repaid for failure to perform.''.

TITLE VI—ACCELERATING THE APPROVAL OF COUNTER-MEASURES

SEC. 601. ACCELERATING THE APPROVAL OF COUNTER-MEASURES.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall facilitate the prompt development, review, and approval of security countermeasures that, pursuant to section 319F–2(c)(6) of the Public Health Service Act, the Secretary has identified for inclusion in the stockpile under section 319F–2(a) of such Act, including, as appropriate, by—

(1) working with such Directors or Administrators as may be appropriate, to facilitate the identification and development of animal models necessary to assess the effectiveness of such countermeasures, if applicable;

(2) meeting and otherwise interacting with the sponsor of an application under the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act for approval of such countermeasure to facilitate the development and clinical

testing of the product necessary for preparation and review of such application;

(3) considering such an application to be a priority, subject to the performance goals established by the Commissioner of Food and Drugs for priority drugs or devices; or

(3) reviewing such an application in reviewable unites, as provided by the Commissioner of Food and Drugs in a pilot for fast-track products under the performance goals established by the Commissioner of Food and Drugs, or providing a modular review, under section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act.

SEC. 602. POSTMARKETING STUDIES FOR COUNTERMEASURES.

(a) NEW DRUGS.—Section 505(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is amended by adding at the end the following:

''(3) POSTMARKETING STUDIES FOR DRUGS APPROVED USING ANIMAL DATA.—

''(A) IN GENERAL.—The sponsor of a drug approved or licensed pursuant to the regulations under subpart I of part 314 or under subpart H of part 601 of title 21, Code of Federal Regulations (as in effect on the date of enact-

ment of the National Biodefense Act of 2005), shall—

"(i) when feasible and ethical, conduct postmarketing studies, according to the plan approved by the Secretary under subparagraph (D), to—

"(I) verify and describe the clinical benefit of the drug when used as indicated; and

"(II) assess the safety of the drug when used as indicated; and

"(ii) immediately submit reports of all data from such studies to the Secretary (excluding names and any other information that identifies a patient or provider).

"(B) FEASIBILITY.—Postmarketing studies under subparagraph (A) shall not be considered feasible until an exigency requiring use of the drug arises.

"(C) DUE DILIGENCE.—When postmarketing studies are feasible, the sponsor shall conduct such studies with due diligence.

"(D) PLAN SUBMISSION AND APPROVAL.—A sponsor shall include, as part of an application under subsection (b) or section 351 of the

Public Health Service Act for which approval is sought under the regulations described in subparagraph (A), a plan for postmarketing study commitments in the event such studies become ethical and feasible. The Secretary shall approve such a plan with modifications deemed necessary by the Secretary.

''(E) PLAN REQUIREMENTS.—Studies required under a plan approved under subparagraph (D) shall include—

''(i) short-term field studies, to be completed after the first, second, and fourth weeks of initial administration of the drug;

''(ii) long-term tracking studies;

''(iii) civilian and military populations; and

''(iv) major population subgroups such as men, women (including pregnant and lactating women), children, the elderly, persons with multiple chronic conditions, and different racial and ethnic subgroups.

''(F) REPORTS ON STUDIES.—The Secretary shall make available—

"(i) to the public, not later than 1 week after submission of data from a study required under subparagraph (A), a summary of the data from such study, including data for the major population subgroups identified in clauses (iii) and (iv) of subparagraph (E); and

"(ii) to any physician or expert in public health, as soon as practicable but in no case later than 30 days after submission, the raw data from such a study.".

(b) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(e)) is amended—

(1) in paragraph (1)(A), by—

(A) redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively; and

(B) inserting after clause (ii), the following:

"(iii)(I) Appropriate postmarketing studies, conducted with due diligence, including short-term field studies (to be completed after the first, second, and fourth weeks of initial administration of the prod-

uct) and long-term tracking studies, civilian and military populations (as appropriate to the declaration under subsection (b)), and major populations subgroups such as men, women (including pregnant and lactating women), children, the elderly, persons with multiple chronic conditions, and different racial and ethnic subgroups, to—

''(aa) verify and describe the clinical benefit of the product when used as indicated; and

''(bb) assess the safety of the product when used as indicated.

''(II) Immediate submission of reports of all data from such studies to the Secretary (excluding names and any other information that identifies a patient or provider).'';

(2) in paragraph (2)(A), by striking ''clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv)'' and inserting ''clauses (i), (ii), and (iii) of paragraph (1)(A), and may establish conditions described in clauses (iv) and (v)''; and

(3) by adding at the end the following:

''(5) REPORTS ON STUDIES.—The Secretary shall make available—

''(A) to the public, not later than 1 week after submission of data from a study required under paragraph (1)(A)(iii) or (2)(A), a summary of the data from such study, including data for the major population subgroups identified in paragraph (1)(A)(iii); and

''(B) to any physician or expert in public health, as soon as practicable but in no case later than 30 days after submission, the raw data from such a study.''.

(c) STUDIES REQUIRED.—The Secretary of Health and Human Services shall conduct the postmarketing studies required by the amendments made by subsection (a) and (b) for any countermeasure that—

(1) is the subject of a declaration under section 224(p)(2) of the Public Health Service Act; and

(2) is not subject to the amendments made by subsection (a) or subsection (b).

(d) COORDINATED SURVEILLANCE.—The Secretary of Health and Human Services, the Secretary of Defense, and the Secretary of Veterans Affairs shall coordinate efforts to collect information on adverse events associated

with the use of vaccines and other countermeasures through both active and passive surveillance, including through the Clinical Immunization Safety Assessment network, the Vaccine Healthcare Centers, and State and local health departments.

TITLE VII—BIODEFENSE INJURY COMPENSATION PROGRAM

SEC. 701. NATIONAL BIODEFENSE INJURY COMPENSATION PROGRAM.

(a) ESTABLISHMENT.—Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

''(q) BIODEFENSE INJURY COMPENSATION PROGRAM.—

''(1) ESTABLISHMENT.—There is established the Biodefense Injury Compensation Program (referred to in this subsection as the 'Compensation Program') under which compensation may be paid for death or any injury, illness, disability, or condition that is likely (based on best available evidence) to have been caused by the administration of a covered countermeasure to an individual pursuant to a declaration under subsection (p)(2).

''(2) ADMINISTRATION AND INTERPRETATION.—The statutory provisions governing the Com-

pensation Program shall be administered and interpreted in consideration of the program goals described in paragraph (4)(B)(iii).

''(3) PROCEDURES AND STANDARDS.—The Secretary shall by regulation establish procedures and standards applicable to the Compensation Program that follow the procedures and standards applicable under the National Vaccine Injury Compensation Program established under section 2110, except that the regulations promulgated under this paragraph shall permit a person claiming injury or death related to the administration of any covered countermeasure to file either—

''(A) a civil action for relief under subsection (p); or

''(B) a petition for compensation under this subsection.

''(4) INJURY TABLE.—

''(A) INCLUSION.—For purposes of receiving compensation under the Compensation Program with respect to a countermeasure that is the subject of a declaration under subsection (p)(2), the Vaccine Injury Table under section 2114 shall be deemed to include death and the injuries, disabilities, illnesses, and conditions

specified by the Secretary under subparagraph (B)(ii).

"(B) INJURIES, DISABILITIES, ILLNESSES, AND CONDITIONS.—

"(i) INSTITUTE OF MEDICINE.—Not later than 30 days after making a declaration described in subsection (p)(2), the Secretary shall enter into a contract with the Institute of Medicine, under which the Institute shall, within 180 days of the date on which the contract is entered into, and periodically thereafter as new information, including information derived from the monitoring of those who were administered the countermeasure, becomes available, provide its expert recommendations on the injuries, disabilities, illnesses, and conditions whose occurrence in one or more individuals are likely (based on best available evidence) to have been caused by the administration of a countermeasure that is the subject of the declaration.

"(ii) SPECIFICATION BY SECRETARY.—Not later than 30 days after the receipt of the expert recommendations de-

scribed in clause (i), the Secretary shall, based on such recommendations, specify those injuries, disabilities, illnesses, and conditions deemed to be included in the Vaccine Injury Table under section 2114 for the purposes described in subparagraph (A).

''(iii) PROGRAM GOALS.—The Institute of Medicine, under the contract under clause (i), shall make such recommendations, the Secretary shall specify, under clause (ii), such injuries, disabilities, illnesses, and conditions, and claims under the Compensation Program under this subsection shall be processed and decided taking into account the following goals of such program:

''(I) To encourage persons to develop, manufacture, and distribute countermeasures, and to administer covered countermeasures to individuals, by limiting such persons' liability for damages related to death and such injuries, disabilities, illnesses, and conditions.

''(II) To encourage individuals to consent to the administration of a covered countermeasure by providing adequate and just compensation for damages related to death and such injuries, disabilities, illnesses, or conditions.

''(III) To provide individuals seeking compensation for damages related to the administration of a countermeasure with a non-adversarial administrative process for obtaining adequate and just compensation.

''(iv) USE OF BEST AVAILABLE EVIDENCE.—The Institute of Medicine, under the contract under clause (i), shall make such recommendations, the Secretary shall specify, under clause (ii), such injuries, disabilities, illnesses, and conditions, and claims under the Compensation Program under this subsection shall be processed and decided using the best available evidence, including information from adverse event reporting or other monitoring of those individuals who were administered

the countermeasure, whether evidence from clinical trials or other scientific studies in humans is available.

''(v) APPLICATION OF SECTION 2116.—Section 2116(b) shall apply to injuries, disabilities, illnesses, and conditions initially specified or revised by the Secretary under clause (ii), except that the exceptions contained in paragraphs (1) and (2) of such section shall not apply.

''(C) RULE OF CONSTRUCTION.—Section 13632 (a)(3) of Public Law 103–66 (107 Stat. 646) (making revisions by Secretary to the Vaccine Injury Table effective on the effective date of a corresponding tax) shall not be construed to apply to any revision to the Vaccine Injury Table made under regulations under this paragraph.

''(5) APPLICATION.—The Compensation Program applies to any death or injury, illness, disability, or condition that is likely (based on best available evidence) to have been caused by the administration of a covered countermeasure to an individual pursuant to a declaration under subsection (p)(2).

''(6) SPECIAL MASTERS.—

''(A) HIRING.—In accordance with section 2112, the judges of the United States Claims Court shall appoint a sufficient number of special masters to address claims for compensation under this subsection.

''(B) BUDGET AUTHORITY.—There are appropriated to carry out this paragraph such sums as may be necessary for fiscal year 2005 and each fiscal year thereafter. This subparagraph constitutes budget authority in advance of appropriations and represents the obligation of the Federal Government.

''(7) COVERED COUNTERMEASURE.—For purposes of this subsection, the term 'covered countermeasure' has the meaning given to such term in subsection (p)(7)(A).

''(8) FUNDING.—Compensation made under the Compensation Program shall be made from the same source of funds as payments made under subsection (p).''.

(b) EFFECTIVE DATE.—This section shall take effect as of November 25, 2002 (the date of enactment of the Homeland Security Act of 2002 (Public Law 107–296; 116 Stat. 2135)).

TITLE VIII—INDEMNIFICATION FOR PRODUCERS OF COUNTERMEASURES

SEC. 801. INDEMNIFICATION FOR MANUFACTURERS AND HEALTH CARE PROFESSIONALS WHO ADMINISTER MEDICAL PRODUCTS NEEDED FOR BIODEFENSE.

Section 224(p) of the Public Health Service Act (42 U.S.C. 233(p)) is amended—

(1) in the subsection heading by striking ''SMALLPOX'';

(2) in paragraph (1), by striking ''against smallpox'';

(3) in paragraph (2)—

(A) in the paragraph heading, by striking ''AGAINST SMALLPOX''; and

(B) in subparagraph (B), by striking clause (ii);

(4) by striking paragraph (3) and inserting the following:

''(3) EXCLUSIVITY; OFFSET.—

''(A) EXCLUSIVITY.—With respect to an individual to which this subsection applies, such individual may bring a claim for relief under—

''(i) this subsection;

"(ii) subsection (q); or

"(iii) part C.

"(B) ELECTION OF ALTERNATIVES.—An individual may only pursue one remedy under subparagraph (A) at any one time based on the same incident or series of incidents. Nothing in the preceding sentence shall be construed to prevent an individual from pursuing a remedy under subparagraph (A) after such individual has elected to decline to pursue another remedy.

"(C) STATUTE OF LIMITATIONS.—For purposes of determining how much time has lapsed when applying statute of limitations requirements relating to remedies under subparagraph (A), any limitation of time for commencing an action, or filing an application, petition, or claim for such remedies, shall be deemed to have been suspended for the periods during which an individual pursues a remedy under such subparagraph.

"(D) OFFSET.—The value of all compensation and benefits provided under part C of this title for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a

claim or suit under this subsection based on the same incident or series of incidents.'';

(5) in paragraph (6)—

(A) in subparagraph (A), by inserting ''or under subsection (q)'' after ''under this subsection''; and

(B) by redesignating subparagraph (B) as subparagraph (C);

(C) by inserting after subparagraph (A), the following:

''(B) GROSSLY NEGLIGENT, RECKLESS, OR ILLEGAL CONDUCT AND WILLFUL MISCONDUCT.—For purposes of subparagraph (A), grossly negligent, reckless, or illegal conduct or willful misconduct shall include the administration by a qualified person of a covered countermeasure to an individual who was not within a category of individuals covered by a declaration under subsection (p)(2) with respect to such countermeasure where the qualified person fails to have had reasonable grounds to believe such individual was within such a category.''; and

(D) by adding at the end the following:

''(D) LIABILITY OF THE UNITED STATES.—The United States shall be liable

under this subsection with respect to a claim arising out of the manufacture, distribution, or administration of a covered countermeasure regardless of whether—

"(i) the cause of action seeking compensation is alleged as negligence, strict liability, breach of warranty, failure to warn, or other action; or

"(ii) the covered countermeasure is designated as a qualified anti-terrorism technology under the SAFETY Act (6 U.S.C. 441 et seq.).

"(E) GOVERNING LAW.—Notwithstanding the provisions of section 1346(b)(1) and chapter 171 of title 28, United States Code, as they relate to governing law, the liability of the United States as provided in this subsection shall be in accordance with the law of the place of injury.

"(F) MILITARY PERSONNEL AND UNITED STATES CITIZENS OVERSEAS.—

"(i) MILITARY PERSONNEL.—The liability of the United States as provided in this subsection shall extend to claims

brought by United States military personnel.

''(ii) CLAIMS ARISING IN A FOREIGN COUNTRY.—Notwithstanding the provisions of section 2680(k) of title 28, United States Code, the liability of the United States as provided for in the subsection shall extend to claims based on injuries arising in a foreign country where the injured party is a member of the United States military, is the spouse or child of a member of the United States military, or is a United States citizen.

''(iii) GOVERNING LAW.—With regard to all claims brought under clause (ii), and notwithstanding the provisions of section 1346(b)(1) and chapter 171 of title 28, United States Code, and of subparagraph (C), as they relate to governing law, the liability of the United States as provided in this subsection shall be in accordance with the law of the claimant's domicile in the United States or most recent domicile with the United States.''; and

(6) in paragraph (7)—

(A) by striking subparagraph (A) and inserting the following:

"(A) COVERED COUNTERMEASURE.—The term 'covered countermeasure', means—

"(i) a substance that is—

"(I)(aa) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

"(bb) vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and

"(II) specified in a declaration under paragraph (2); or

"(ii) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act), biological product (as such term is defined in section 351(i) of this Act), or device (as such term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) that—

"(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to treat, identify, or prevent harm from any bio-

logical, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

"(II) is—

"(aa) authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act, so long as the manufacturer of such drug, biological product, or device has—

"(AA) made all reasonable efforts to obtain applicable approval, clearance, or licensure; and

"(BB) cooperated fully with the requirements of the Secretary under such section 564; or

''(bb) approved or licensed solely pursuant to the regulations under subpart I of part 314 or under subpart H of part 601 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the National Biodefense Act of 2005); and

''(III) is specified in a declaration under paragraph (2).''; and

(B) in subparagraph (B)—

(i) by striking clause (ii), and inserting the following:

''(ii) a health care entity, a State, or a political subdivision of a State under whose auspices such countermeasure was administered;'' and

(vi) in clause (viii), by inserting before the period ''if such individual performs a function for which a person described in clause (i), (ii), or (iv) is a covered person''.

TITLE IX—STRENGTHENING PUBLIC HEALTH READINESS FOR PANDEMICS

Subtitle A—Improved Planning for Pandemic Influenza

SEC. 901. FEDERAL PANDEMIC INFLUENZA PREPAREDNESS PLAN.

Not later than 10 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue in final form a Pandemic Influenza Preparedness Plan to provide for a coordinated Federal, State, and local preparation and response to an influenza pandemic.

SEC. 902. REQUIREMENT TO DEVELOP STATE PANDEMIC INFLUENZA PLANS.

(a) IN GENERAL.—In fiscal years after the fiscal year in which the Secretary issues the Plan described in section 901, the Secretary shall withhold from a State that has not submitted to the Secretary an acceptable State pandemic influenza plan (as determined by the Secretary) the amounts described in subsection (b) for each fiscal year for which such a plan is not submitted. The Secretary shall develop criteria for what constitutes an acceptable State plan based on the Plan described in section 901.

(b) AMOUNTS DESCRIBED.—The amounts described in this subsection with respect to a State described in sub-

section (a) are the following amounts that are payable to a State for a fiscal year under section 319C, 319C–1, or 319C–2 of the Public Health Service Act or from the Public Health and Social Services Emergency Fund (or any successor to such Fund):

(1) For the first fiscal year after the initial year in which the Secretary of Health and Human Services issues the Plan described in section 901, an amount equal to 10 percent of the amount the State was eligible to receive for such fiscal year.

(2) For the second such fiscal year, an amount equal to 15 percent of the amount the State was eligible to receive for such fiscal year.

(3) For the third such fiscal year, an amount equal to 20 percent of the amount the State was eligible to receive for such fiscal year.

(4) For the fourth and each subsequent fiscal years, an amount equal to 25 percent of the amount the State was eligible to receive for such fiscal year.

(c) DISTRIBUTION.—The Secretary shall redistribute amounts withheld under this section to compliant States in proportion to the populations of such States.

(d) PLANNING GRANTS.—The Secretary shall award planning grants to States to assist such States in preparing or enhancing the plans described in subsection (a).

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2006 through 2010.

SEC. 903. USE OF CDC AND HRSA FUNDS FOR PUBLIC HEALTH PREPAREDNESS.

(a) APPLICABILITY OF PRIORITY STATEMENT TO CDC PREPAREDNESS PROGRAMS.—

(1) IN GENERAL.—The statement of priorities described in section 319C–1(e) of the Public Health Service Act shall apply to awards made by the Centers for Disease Control and Prevention—

(A) from amounts under the Public Health and Social Services Emergency Fund (or any successor to such Fund); and

(B) under the Public Health Preparedness and Response for Bioterrorism program or any successor to such program.

(2) LIMITATION.—No State that receives as award under a program described in paragraph (1) may deny funding or impose any other sanction against an entity that uses funds received under such program to enhance preparedness for naturally occurring outbreaks of infectious disease.

(2) APPLICABILITY OF PRIORITY STATEMENT TO HRSA PREPAREDNESS PROGRAMS.—

(1) IN GENERAL.—The statement of priorities described in section 319C–2(g) of the Public Health Service Act shall apply to awards made by the Health Resources and Service Administration—

(A) from amounts under the Public Health and Social Services Emergency Fund (or any successor to such Fund); and

(B) under the National Bioterrorism Hospital Preparedness Program or any successor to such program.

(2) LIMITATION.—No State that receives as award under a program described in paragraph (1) may deny funding or impose any other sanction against an entity that uses funds received under such program to enhance preparedness for naturally occurring outbreaks of infectious disease.

Subtitle B—Vaccine Supply

SEC. 911. BUY-BACK PROGRAM FOR FLU VACCINE.

(a) REQUESTS FOR MORE DOSES.—

(1) IN GENERAL.—Not later than March 15 of each year, the Secretary of Health and Human Services shall enter into contracts with manufacturers to

produce such additional doses of the influenza vaccine as determined necessary by the Secretary.

(2) CONTENT OF CONTRACT.—A contract for additional doses shall provide that the manufacturer will be compensated by the Secretary at an equitable rate negotiated by the Secretary and the manufacturer for any doses that—

(A) were not sold by the manufacturer through routine market mechanisms at the end of the influenza season for that year; and

(B) were requested by the Secretary to be produced by such manufacturer.

(3) WHEN SUCH VACCINE PURCHASES SHOULD TAKE PLACE.—The Secretary of Health and Human Services may purchase from the manufacturer the doses for which it has contracted at any time after which it is determined by the Secretary, in consultation with the manufacturer, that the doses will likely not be absorbed by the private market.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

Subtitle C—Enhancing the National Strategic Stockpile

SEC. 921. STOCKPILING OF ANTIVIRALS AND OTHER MEDICATIONS.

(a) IN GENERAL.—Section 319F–2(b) of the Public Health Service Act (42 U.S.C. 247d–6b(b)) is amended—

(1) by striking the subsection heading and inserting the following: ''STOCKPILING NATIONAL PRIORITY COUNTERMEASURES''; and

(2) by adding at the end the following:

''(3) MEDICATION FOR PANDEMIC INFLUENZA.—

''(A) IN GENERAL.—The Secretary shall ensure that the stockpile described in subsection (a) includes an amount of antiviral medication sufficient to provide for the emergency health security of the United States (including the emergency health security of children and other vulnerable populations) with respect to strains of influenza that may (in the determination of the Secretary) contribute to a pandemic.

''(B) AMOUNT AND TYPE.—In determining the types and amounts of the antivirals and other medications to be placed in the stockpile under subparagraph (A), the Secretary shall

take into account the recommendations of the World Health Organization and of professional societies with expertise in infectious diseases.

''(C) AUTHORIZATION OF APPROPRIATIONS.—

''(i) IN GENERAL.—There is authorized to be appropriated to carry out subparagraph (A), $3,080,000,000 for fiscal year 2006. Amounts appropriated under this paragraph shall remain available until expended.

''(ii) REALLOCATION OF UNEXPENDED AMOUNTS.—The Secretary shall reallocate amounts appropriated under clause (i) that are not utilized by the Secretary for the purchase of antivirals under such clause, for activities under sections 319C–1 and 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3a and 247d–3b). Such amounts shall be reallocated equally between such sections.''.

(b) TECHNICAL AMENDMENT.—Section 319F–2(a)(1) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(1)) is amended by inserting ''(including drugs, biologics, and devices to address acute exacerbation of chron-

ic illness and mental health disorders)'' after ''other supplies''.

SEC. 922. STRATEGIC PLAN FOR STOCKPILE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall develop a comprehensive plan for the use of each medical intervention contained in the national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh–12).

(b) REQUIREMENTS OF PLAN.—The plan developed under subsection (a) shall—

(1) cover all relevant Federal, State, and local agencies as well as necessary members of the private sector;

(2) with respect to all products in the stockpile, provide for the coordination of activation, distribution, and dissemination of such products to the population at large and to specific high-risk groups such as health care professionals;

(3) with respect to new medicines or vaccines that are added to the stockpile, provide, within a reasonable period of time, for the coordination of activation, distribution, and dissemination of the prod-

uct to the population at large and specific high-risk groups such as health care professionals; and

(4) include procedures for triage or other methods to prioritize the distribution of materials from the stockpile in the event of multiple transit attacks or other public health emergencies occurring simultaneously in different areas of the nation.

(c) PERIODIC UPDATING.—The plan developed under subsection (a) shall be periodically reviewed and updated to ensure the consideration of the needs of the changing nature of threats, the State of medical practice, and the capacities of the agencies and organizations involved.

Subtitle D—Prohibiting Price Gouging on Needed Flu Medicines

SEC. 931. UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN COMMERCE RELATED TO TREATMENTS FOR PANDEMIC INFLUENZA.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by adding at the end the following:

''(g) UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN COMMERCE RELATED TO TREATMENTS FOR PANDEMIC INFLUENZA.—

''(1) SALES TO CONSUMERS AT UNCONSCIONABLE PRICE.—

"(A) IN GENERAL.—During any public health emergency declared by the Secretary under section 319 related to pandemic influenza, it shall be unlawful for any person to sell any drug (including an anti-viral drug), device, or biologic for the prevention or treatment of influenza in, or for use in, the area to which that declaration applies at a price that—

"(i) is unconscionably excessive (as determined by the Secretary); or

"(ii) indicates the seller is taking unfair advantage of the circumstances to increase prices unreasonably.

"(B) FACTORS TO BE CONSIDERED.—In determining whether a violation of paragraph (1) has occurred, a court shall take into account, among other factors, whether—

"(i) the amount charged represents a gross disparity between the price of a drug, device, or biologic for the prevention or treatment of influenza and the price at which the drug, device, or biologic was offered for sale in the usual course of the seller's business immediately prior to the public health emergency; or

"(ii) the amount charged grossly exceeds the price at which the same or similar drug, device, or biologic for the prevention or treatment of influenza was readily obtainable by other purchasers in the area in which the declaration applies.

"(C) MITIGATING FACTORS.—In determining whether a violation of subparagraph (A) has occurred, the court shall also take into account, among other factors, the price that would reasonably equate supply and demand in a competitive and freely functioning market and whether the price at which the drug, device, or biologic for the prevention or treatment of influenza was sold reasonably reflects additional costs, not within the control of the seller, that were paid or incurred by the seller.

"(2) FALSE PRICING INFORMATION.—It shall be unlawful for any person to report information related to the wholesale price of any drug, device, or biologic for the prevention or treatment of influenza to the Secretary if—

"(A) that person knew, or reasonably should have known, the information to be false or misleading;

''(B) the information was required by law to be reported; and

''(C) the person intended the false or misleading data to affect data compiled by the department or agency involved for statistical or analytical purposes with respect to the market for drugs, devices, or biologics for the prevention or treatment of influenza.

''(3) MARKET MANIPULATION.—It shall be unlawful for any person, directly or indirectly, to use or employ, in connection with the purchase or sale of drugs, devices, or biologics for the prevention or treatment of influenza at wholesale, any manipulative or deceptive device or contrivance, in contravention of such rules and regulations as the Secretary may prescribe as necessary or appropriate in the public interest or for the protection of United States citizens.''.

Subtitle E—National Institute of Pathology

SEC. 941. NATIONAL INSTITUTE OF PATHOLOGY.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) In section 401(b)(2), by adding at the end the following:

''(H) The National Institute of Pathology.''; and

(2) by adding at the end of part E (42 U.S.C. 287 et seq.) the following:

''Subpart 7—National Institute of Pathology

''SEC. 485A. ESTABLISHMENT OF NATIONAL INSTITUTE OF PATHOLOGY.

''In order to provide pathology consultation for civilian and military health professionals (including Department of Veterans Affairs health professionals) there is established the National Institute of Pathology (in this subpart referred to as the 'Institute'). The Institute shall be headed by a director, who shall be appointed by the Secretary. The Director of the Institute shall report directly to the Director of NIH.

''SEC. 485B. PURPOSES AND FUNCTIONS OF THE INSTITUTE.

''(a) PURPOSES OF THE INSTITUTE.—The general purposes of the Institute are to—

''(1) conduct and support research, education, training, and other programs with respect to the science and clinical practice of pathology;

''(2) maintain and improve a pathology tissue repository; and

''(3) provide pathology consultation services.

''(b) ACTIVITIES OF THE DIRECTOR.—In order to carry out the purposes of the Institute described in subsection (a), the Director of the Institute—

''(1) shall—

''(A) maintain and improve a comprehensive repository of pathological specimens;

''(B) provide consultations on request regarding clinical cases;

''(C) conduct educational programs and publish educational materials on the science and clinical practice of pathology;

''(D) maintain and improve registries on such clinical conditions as the Director of the Institute determines appropriate; and

''(E) conduct and support research on pathology; and

''(2) may—

''(A) collect reasonable and appropriate fees for the activities described in paragraph (1)(B); and

''(B) conduct such other activities as the Director of the Institute determines appropriate to carry out the purposes described in subsection (a).

''(c) AUTHORITY FOR EXPERT OPINIONS.—The Director of the Institute may enter into memoranda of understanding with officials at the Department of Veterans Affairs and the Department of Defense to provide expert second opinion pathology consultations and pathology education or training if the Secretary of either such Department determines that such provision would be in the best interest of either of their respective departments.

''SEC. 485C. BOARD OF REGENTS.

''(a) MEMBERSHIP.—

''(1) IN GENERAL.—There is established a Board of Regents of the Institute (in this subpart referred to as the 'Board') consisting of—

''(A) the Surgeons General of—

''(i) the Public Health Service;

''(ii) the Army;

''(iii) the Navy; and

''(iv) the Air Force;

''(B) the Chief Medical Director of the Department of Medicine and Surgery of the Department of Veterans Affairs;

''(C) the Deputy Director of the National Library of Medicine;

''(D) the Assistant Secretary of Health of the Department of Defense;

''(E) the Dean of the Uniformed Services University of the Health Sciences; and

''(F) 11 members to be appointed by the Secretary from among leaders in pathology research, education and clinical practice.

''(2) EX OFFICIO MEMBERS.—The members of the Board described in subparagraphs (A) through (E) of paragraph (1) shall serve as ex officio members of the Board.

''(3) CHAIRPERSON.—The members of the Board appointed under paragraph (1)(F) shall annually elect one of such members to serve as the Chairperson of the Board until the next election.

''(b) DUTIES OF THE BOARD.—It shall be the duty of the Board to advise, consult with, and make recommendations to the Director of NIH on important matters of policy in regard to the Institute, including such matters as the scope, content and organization of the research, education and consultative services provided by the Institute. The Board shall make recommendations to the Director of NIH regarding the rules under which specimens from the tissue repository will be used and under which it's publications, facilities and services will be made available to various kinds users

''(c) TERMS OF OFFICE.—Each appointed member of the Board shall hold office for a term of 4 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within 1 year after the end of the preceding term of such member.

''(d) COMPENSATION.—Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of the Board, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c).

''SEC. 485D. GIFTS TO THE INSTITUTE.

''Section 231 shall be applicable to the acceptance and administration of gifts made for the benefit of the Institute or for carrying out any of its functions.

''SEC. 485E. INSTITUTE FACILITIES.

''There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Institute. The Administrator of General Services may acquire, by

purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.''.

SEC. 942. TRANSFER OF THE ARMED FORCES INSTITUTE OF PATHOLOGY.

(a) IN GENERAL.—

(1) IN GENERAL.—Except as provided in paragraph (2), there are transferred to the National Institute of Pathology established under subpart 7 of part E of title IV of the Public Health Service Act all functions, duties, personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations of the Armed Forces Institute of Pathology. The preceding sentence shall not affect any proceedings, pending applications, suits, or other actions pending on the date of enactment of this Act.

(2) EXCEPTIONS.—The following components of the Armed Forces Institute of Pathology shall not be transferred from the Department of Defense pursuant to paragraph (1):

(A) The Armed Forces Medical Examiner.

(B) The Department of Defense DNA registry.

(C) Accident Investigation Program.

(D) The histopathology training program.

(E) The patient safety center.

(F) Department of Legal Medicine.

(G) Center for Clinical Laboratory Medicine.

(H) Drug Testing and Quality Assurance Program.

(I) Subject to the discretion of the Secretary of Defense, medical research programs on the following:

(i) Body armor.

(ii) Environmental sarcoidosis.

(iii) Depleted uranium.

(iv) Military working dogs.

(v) Such other areas of research related to pathology as the Secretary of Defense shall choose to conduct.

(b) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or relating to the Armed Forces Institute of Pathology shall be deemed to be a reference to the National Institute of Pathology established under subpart 7 of part E of title IV of the Public Health Service Act.

Subtitle F—Increased Influenza Vaccine and Outbreak Surveillance Activities

SEC. 951. TRACKING NETWORK AND DEMONSTRATION GRANTS.

Title III of the Public Health Service Act is amended by inserting after section 319B (42 U.S.C. 247d–2) the following:

"SEC. 319B-1. TRACKING NETWORK AND DEMONSTRATION GRANTS.

''(a) TRACKING SYSTEM.—

''(1) ESTABLISHMENT.—Not later than 2 years after the date of enactment of this section, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local public health officials, shall establish an electronic tracking system through which the Director and such officials can determine the amount of influenza vaccine that

is available for distribution to patients, as well as the need for such vaccine on a county-by-county basis, and the progress of vaccine delivery and distribution efforts at the State and local level.

''(2) ESTIMATES.—The tracking system established under paragraph (1) shall collect estimates of the size of high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this section as 'high priority populations') in each county in the United States, so as to better determine where influenza vaccine resources may need to be directed in the case of an emergency.

''(3) PROVISION OF INFORMATION.—To be eligible to participate in the program under section 911 the vaccine manufacturer shall provide information to the tracking system as the Director of the Centers for Disease Control and Prevention determines appropriate in accordance with subtitle 3 of title XXI.

''(4) DATABASE.—In consultation with manufacturers, distributors, wholesalers, and State and local health departments, the Secretary shall develop guidelines for the development and use of a database

in order to maintain confidentiality and ensure that none of the information provided under paragraph (3) and contained in the database can be used to provide a proprietary advantage within the vaccine market while allowing State and local health officials such information to maximize the delivery and availability of vaccines to high priority populations.

''(b) EXPANSION OF CURRENT SYSTEMS AND ACTIVITIES.—

''(1) SURVEILLANCE SYSTEM.—Not later than 4 years after the date of enactment of this section, the Director of the Centers for Disease Control and Prevention shall upgrade the influenza surveillance system of the Centers for Disease Control and Prevention to report influenza data from State and local health departments into the tracking system established under subsection (a)(1).

''(2) EDUCATIONAL MATERIALS.—The tracking system shall contain information to assist users in accessing influenza education, outreach, and communications tools.

''(3) EMERGENCY PROVIDER DATABASE.—The Director of the Centers for Disease Control and Prevention shall coordinate access to, in conjunction with State and local health departments and State

licensing boards for health professionals, a database registry of medical personnel who can provide services in the event of a health emergency, including pandemic influenza or an influenza vaccine shortage. Such information shall be made available through the tracking network.

''(c) DEMONSTRATION GRANTS.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall award demonstration grants to State and local health departments to enable such departments to enter into contract with hospitals, community health centers, long-term care facilities, physicians' offices, and health care facilities operated or funded by such departments to assist such entities in upgrading their information technology, and workforce in a manner that will allow such entities to improve their ability to report and track influenza vaccine dissemination.

''(2) PRIORITY.—In awarding grants under paragraph (1), priority shall be given to entities that serve high priority populations in medically underserved areas.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

''(1) to carry out subsection (a), $100,000,000 for each of fiscal years 2007 through 2011, of which $500,000 for each fiscal year shall be made available to implement subsection (b)(3); and

''(2) to carry out subsection (c), $100,000,000 for each of fiscal years 2007 through 2011.''.

SEC. 952. EDUCATIONAL EFFORTS AND GRANTS.

Title III of the Public Health Service Act is amended by inserting after section 319B–1 (as added by section 951) the following:

''SEC. 319B–2. IMMUNIZATION EDUCATIONAL EFFORTS AND GRANTS.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall revise and expand the influenza-related educational materials to the Centers for Disease Control and Prevention, and facilitate the use of such materials by health care providers and patients. The Director is authorized to coordinate such educational efforts with nonprofit provider and patient advocacy groups.

''(b) INFLUENZA VACCINE EDUCATION AND OUTREACH.—

''(1) IN GENERAL.—In order to achieve an optimal balance in the influenza vaccine market, and to ensure that the recommendations of the Advisory

Committee on Immunization Practices to the Centers for Disease Control and Prevention for vaccine administration are carried out to the maximum extent possible, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall carry out influenza immunization education and outreach activities that target physicians and other health care providers, health insurance providers, health care institutions and patients, particularly those in high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this section as 'high priority populations').

''(2) TYPES OF ACTIVITIES.—The education and outreach activities under paragraph (1) shall include—

''(A) activities to encourage voluntary participation in influenza vaccination programs, with the goal of increasing overall influenza vaccination rates in the United States, achieving full influenza vaccination of all high priority populations, and full use of each season's influenza vaccine supply;

''(B) the provision of information on influenza prevention;

''(C) activities to increase the number of healthcare providers who receive influenza vaccines each year; and

''(D) other influenza educational efforts determined appropriate by the Director.

''(c) GRANTS.—The Director of the Centers for Disease Control and Prevention may award grants to State and local health departments to carry out activities to encourage individuals, particularly those from high priority populations, to seek out influenza vaccinations.

''(d) COLLABORATION.—State and local health departments that receive grants under subsection (b) are encouraged to collaborate on projects with physicians and other health care providers, health insurance providers, health care institutions, and groups representing high priority populations.

''(e) AUTHORIZATION OF APPROPRIATIONS.—In addition to any amounts otherwise available through the Secretary for influenza outreach and education, there is authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2007 through 2011.''.

Subtitle G—Miscellaneous Provisions

SEC. 961. HRSA CURRICULUM DEVELOPMENT AND TRAINING PROGRAMS.

In carrying out activities under section 319F(g) of the Public Health Service Act and any related activities on the development of training program for health professionals in the recognition of the signs and symptoms of exposure to a potential bioweapon and other agents that may create a public health emergency (including the Bioterrorism Training and Curriculum Development program of the Health Resources and Services Administration), the Secretary of Health and Human Services shall, to the maximum extent practicable, provide awards to a single entity or a small number of entities that have the capacity to provide consistent training nationwide. In carrying out the requirement of the preceding sentence, the Secretary may not, except if there is no practicable alternative, provide awards to any single entity that is less than 20 percent of the total awards made for any fiscal year.

SEC. 962. USING HEALTH INFORMATION TECHNOLOGY TO ENAHNCE EPIDEMIC DETECTION.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by adding at the end the following:

''(k) USING HEALTH INFORMATION TECHNOLOGY TO ENHANCE EPIDEMIC DETECTION.—

''(1) IN GENERAL.—The Secretary may award demonstration grants to eligible entities to enable such entities to establish or enhance information technology systems for the rapid detection of infectious disease outbreaks.

''(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), an entity shall—

''(A) be a State or local government or nonprofit entity; and

''(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including and assurance that the entity will submit to the Secretary a report on the effective of the systems funded under the grant.

''(3) EVALUATION OF SYSTEMS.—Not later than 1 year after the date of enactment of this subsection, and annually thereafter, the Director of the Centers for Disease Control and Prevention shall conduct an evaluation of the systems implemented under grants under this subsection to determined which systems are most effective. The Director shall

issue recommendations on best practices for such systems.

''(4) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of this subsection, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subsection.

''(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $50,000,000 for each of fiscal years 2006 through 2010.''.

SEC. 963. NATURALLY OCCURRING OR DELIBERATELY INTRODUCED AGENTS.

Section 319C–1(d)(7)(A) of the Public Health Service Act (42 U.S.C. 247d–3a(d)(7)(A)) is amended by inserting ''(where such biological agent may be naturally occurring or deliberately introduced)'' after ''agent''.

SEC. 964. USE OF FEDERAL FACILITIES IN EMERGENCIES.

(a) IDENTIFICATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall identify Federal facilities that are capable of being used to provide health care as surge

capacity hospitals during a public health emergency under section 319 of the Public Health Service Act.

(b) MEMORANDUM OF UNDERSTANDING.—The Secretary of Health and Human Services may enter into a memorandum of understanding with the heads of appropriate Federal agencies and other workforce groups to utilize the facilities identified under subsection (a) during a public health emergency under section 319 of the Public Health Service Act.

SEC. 965. ADVISORY COMMITTEE ON VULNERABLE POPULATIONS.

(a) IN GENERAL.—Section 319F(b)(2) of the Public Health Service Act (42 U.S.C. 247d–6(b)(2)) is amended to read as follows:

''(2) NATIONAL ADVISORY COMMITTEE ON VULNERABLE POPULATIONS AND TERRORISM.—

''(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on Vulnerable Populations and Terrorism (referred to in this paragraph as the 'Advisory Committee').

''(B) DUTIES.—The Advisory Committee shall—

''(i) provide recommendations regarding—

''(I) the preparedness of the health care (including mental health care) system to respond to bioterrorism as it relates to children, pregnant women, and other vulnerable populations;

''(II) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of children, pregnant women, and other vulnerable populations; and

''(III) changes, if necessary, to the national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of children, pregnant women, and other vulnerable populations; and

''(ii) advise the National BioVenture Trust with respect to granting priority to

supporting and facilitating research and development of countermeasures, and formulations of countermeasures, that are likely to be safe and effective for children, pregnant women, and other vulnerable populations.

''(C) COMPOSITION.—The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of children, pregnant women, and other populations and health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines.''.

(b) ANNUAL REVIEW OF STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in consultation with the National Advisory Committee on Vulnerable Populations and Terrorism and other experts as determined appropriate by the Secretary, shall annually conduct a review of—

(A) the capacity of the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) to address the emergency health needs of pediatric

populations, pregnant women, and other vulnerable populations; and

(B) any formulary additions or modifications with respect to the contents of such Stockpile to ensure that the needs of such populations are met.

(2) RECOMMENDATIONS.—Based on the review under paragraph (1), the Secretary shall—

(A) determine and prioritize recommendations of formulary additions to the Strategic National Stockpile with respect to pediatric populations, pregnant women, and other vulnerable populations; and

(B) submit such recommendations to Congress.

SEC. 966. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

Section 319I(a) of the Public Health Service Act (42 U.S.C. 247d–7b(a)) is amended by striking ''maintain a system'' and inserting ''maintain a single system''.

TITLE X—ENHANCING ANTIBIOTICS

SEC. 1001. PRESERVING THE EFFECTIVENESS OF MEDICALLY IMPORTANT ANTIBIOTICS.

(a) PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.—

(1) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(nn) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—The term 'critical antimicrobial animal drug' means a drug that—

''(1) is intended for use in food-producing animals; and

''(2) is composed wholly or partly of—

''(A) any kind of penicillin, tetracycline, bacitracin, macrolide, lincomycin, streptogramin, aminoglycoside, sulfonamide; or

''(B) any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

''(oo) NONTHERAPEUTIC USE.—The term 'nontherapeutic use', with respect to a critical antimicrobial animal drug, means any use of the drug as a feed or water addi-

tive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.''.

(2) NONTHERAPEUTIC USE.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended—

(A) in the first sentence—

(i) in subparagraph (H), by striking ''or'' at the end;

(ii) by redesignating subparagraph (I) as subparagraph (J); and

(iii) by inserting after subparagraph (H) the following:

''(I) with respect to a critical antimicrobial animal drug or a drug of the same chemical class as a critical antimicrobial animal drug, the applicant has failed to demonstrate that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable, in whole or in part, to the nontherapeutic use of the drug; or''; and

(B) in the second sentence, by striking ''(A) through (I)'' and inserting ''(A) through (J)''.

(3) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—

''(1) APPLICABILITY.—This subsection applies to the nontherapeutic use in a food-producing animal of—

''(A)(i) a drug that is a critical antimicrobial animal drug; or

''(ii) a drug that is of the same chemical class as a critical antimicrobial animal drug; and

''(B) a drug—

''(i) for which, as of the day before the date of enactment of this subsection, there was in effect an approval of an appli-

cation filed under subsection (b) or (j) of section 505; or

''(ii) that was otherwise marketed for use.

''(2) WITHDRAWAL.—The Secretary shall withdraw the approval of a nontherapeutic use in food-producing animals described in paragraph (1) on the date that is 2 years after the date of enactment of this subsection unless—

''(A) before the date that is 2 years after that date of enactment, the Secretary makes a written determination that the holder of the approved application has demonstrated that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug; or

''(B) before the date specified in subparagraph (A), the Secretary makes a final written determination under this subsection, with respect to a risk analysis of the drug conducted by the Secretary and other relevant information, that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable

in whole or in part to the nontherapeutic use of the drug.

''(3) EXEMPTIONS.—Except as provided in paragraph (5), if the Secretary grants an exemption under section 505(i) for a drug that is a critical antimicrobial animal drug, the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, as of the date that is 2 years after the date on which the Secretary grants the exemption.

''(4) APPROVALS.—If an application for a drug that is critical antimicrobial animal drug is submitted to the Secretary under section 505(b), the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, as of the date that is 2 years after the date on which the application is submitted to the Secretary.

''(5) EXCEPTION.—Paragraph (3) or (4), as the case may be, shall not apply if, before the date on which approval would be rescinded under that sub-

paragraph, the Secretary determines that the holder of the approved application has demonstrated that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable, in whole or in part, to the nontherapeutic use in the food-producing animal of the critical antimicrobial animal drug.''.

(b) ASSISTANCE TO DEFRAY EXPENSES OF LIVESTOCK OR POULTRY PRODUCERS IN PHASING OUT NONTHERAPEUTIC USE OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.—

(1) DEFINITIONS.—In this subsection, the terms ''critical antimicrobial animal drug'' and ''nontherapeutic use'' have the meanings given the terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) PAYMENTS.—The Secretary of Agriculture may make payments to producers of livestock or poultry that the Secretary determines are substantially reducing, or have substantially reduced, the nontherapeutic use of critical antimicrobial animal drugs in livestock or poultry in order to defray the costs of such reduction.

(3) PRIORITY FOR FAMILY FARMERS AND SMALL FARMS.—In awarding payments under para-

graph (2), the Secretary of Agriculture shall give priority to family-owned and family-operated farms or ranches and to small farms or ranches, as determined by the Secretary.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this subsection for fiscal year 2005 and for each subsequent fiscal year.

(c) RESEARCH AND DEMONSTRATION PROGRAMS.—Subtitle D of title VII of the Farm Security and Rural Investment Act of 2002 (116 Stat. 455) is amended by adding at the end the following:

"SEC. 7413. PHASING OUT OF NONTHERAPEUTIC USE OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.

''(a) DEFINITIONS.—In this section, the terms 'critical antimicrobial animal drug' and 'nontherapeutic use' have the meanings given the terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

''(b) GRANTS.—The Secretary, in consultation with the Secretary of Health and Human Services, shall award grants to colleges and universities to establish research and demonstration programs for—

''(1) phasing out the nontherapeutic use of critical antimicrobial animal drugs in livestock or poultry; and

''(2) informing livestock and poultry producers of methods for accomplishing the objective described in paragraph (1).

''(c) EDUCATION.—The Secretary shall use the results of the research and demonstration programs and the experience of agricultural producers that have reduced or eliminated the nontherapeutic use of critical antimicrobial animal drugs to educate other agricultural producers, through the Cooperative Research, Education, and Extension Service, concerning how to successfully phase out such use in livestock or poultry.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section for fiscal years 2004 through 2007.''.

(d) COLLECTION OF DATA ON CRITICAL ANTIMICROBIAL ANIMAL DRUGS.—

(1) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 512 (21 U.S.C. 360b) the following:

''SEC. 512A. COLLECTION OF DATA ON CRITICAL ANTIMICROBIAL ANIMAL DRUGS.

''(a) IN GENERAL.—Not later than July 1 of each year, a manufacturer of a critical antimicrobial animal drug or an animal feed for food-producing animals bearing

or containing a critical antimicrobial animal drug shall submit to the Secretary a report, in such form as the Secretary shall require, containing information on the sales during the previous calendar year of the critical antimicrobial animal drug or animal feed.

''(b) INFORMATION TO BE INCLUDED.—A report under subsection (a) shall—

''(1) state separately the quantity of the critical antimicrobial animal drug, including in animal feed bearing or containing the critical antimicrobial animal drug, sold for each kind of food-producing animal;

''(2) describe the claimed purpose of use for each kind of food-producing animal as being for growth promotion, weight gain, feed efficiency, disease prevention, disease control, disease treatment, or another purpose; and

''(3) describe the dosage form of the drug.

''(c) PUBLICATION.—

''(1) IN GENERAL.—The Secretary shall—

''(A) make the information submitted under subsection (a) available to the public; and

''(B) publish the information at least annually.

''(2) PROTECTION OF CONFIDENTIALITY.—The Secretary shall aggregate information, if necessary, to avoid disclosure under paragraph (1) of confidential business information.''.

(2) PROHIBITED ACTS.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by striking ''515(f)'' and inserting ''512A, 515(f),''.

(3) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2005.

(e) LIMITATION ON ANTIBIOTIC USES.—If a countermeasure that is developed using assistance provided under the Project BioShield Program (under the Project BioShield Act of 2004, and the amendments made by such Act) is an antibiotic (as defined for purposes of the Federal Food, Drug, and Cosmetic Act)—

(1) such countermeasure may not be used for nontherapeutic uses (as defined in section 201(oo) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) in animals; and

(2) the Secretary of Health and Human Services shall transfer from the BioShield fund an amount equal to 10 percent of the funds provided to the programs authorized under section 319E of the

Public Health Service Act (42 U.S.C. 247d–5) for purposes of funding the countermeasure.

TITLE XI—IMPROVING RESEARCH ON BIODEFENSE COUNTERMEASURES

SEC. 1101. IMPROVING THE ABILITY OF BIODEFENSE RESEARCHERS TO WORK WITH SELECT AGENTS.

Section 351A of the Public Health Service Act (42 U.S.C. 262a) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(B)(ii), by inserting ", and with the Advisory Committee established under subsection (m) in the manner described in paragraph (3) of such subsection" before the period; and

(B) by striking paragraph (2), and inserting the following:

"(2) BIENNIAL REVIEW.—

"(A) IN GENERAL.—The Secretary shall, on a biennial or more frequent basis as determined appropriate, review and republish the list established under paragraph (1), and by regulation revise such list as necessary in accordance with such paragraph.

''(B) CONSULTATION.—In carrying out the activities described in subparagraph (A), the Secretary shall consult with the Advisory Committee established under subsection (m) in the manner described in paragraph (3) of such subsection.'';

(2) in subsection (e)(3), by adding at the end the following:

''(D) PRESUMPTION OF ALLOWED ACCESS.—

''(i) IN GENERAL.—If an individual described in subclause (I) or (II) of clause (iii) transfers employment or professional affiliation from one registered person (referred to in this subparagraph as the 'sender') to another registered person (referred to in this subparagraph as the 'recipient'), and the recipient determines that such individual is an individual described in paragraph (2)(A), the recipient shall take the actions described in paragraph (2) with respect to such individual.

''(ii) TREATMENT DURING ATTORNEY GENERAL REVIEW.—During the period in which the Attorney General is conducting a

review pursuant to this paragraph with respect to an individual described in clause (i), such individual shall be presumed not to be an individual described in clauses (i) or (ii) of subparagraph (B).

''(iii) INDIVIDUAL DESCRIBED.—An individual described in this clause is—

''(I) an individual the name of whom the sender has submitted to the Secretary and the Attorney General under paragraph (2)(B) and whom the Attorney General has determined is not described in clause (i) or (ii) of subparagraph (B); or

''(II) an individual who is a registered person under paragraph (6)(A).

''(iv) Not later than 180 days after the date of enactment of this subparagraph, the Secretary shall promulgate regulations to implement this subparagraph.'';

(3) by redesignating subsection (m) as subsection (p); and

(4) by inserting after subsection (l), the following:

''(m) SELECT AGENT SCIENTIFIC ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT.—The Secretary shall establish a Select Agent Advisory Committee (referred to in this section as the 'Advisory Committee') to consult with, and provide expert advice to, the Secretary and the Secretary of Agriculture in the manner described in paragraph (3).

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The Advisory Committee shall be composed of individuals, to be appointed by the Secretary, having expertise in scientific research with select agents or other microbial or viral pathogens.

''(B) TERMS.—An individual appointed under subparagraph (A) shall serve for a 2-year term. The terms of the initial members appointed under such subparagraph shall be staggered as determined by the Secretary,

''(3) CONSULTATION AND RESPONSE.—

''(A) IN GENERAL.—Except during a public health emergency, the Secretary shall, not later than 90 days prior to promulgating a regulation under this section, transmit a draft of such regulation to the Advisory Committee.

''(B) COMMENTS AND RECOMMENDATIONS.—The Advisory Committee may submit to the Secretary comments and recommendations regarding a draft regulation submitted by the Secretary under subparagraph (A).

''(C) With respect to any recommendations submitted by the Advisory Committee under subparagraph (B) relating to a draft regulation during the 60-day period beginning on the date on which such draft regulation was transmitted to the Advisory Committee, the Secretary shall, prior to promulgating such regulation—

''(i) modify the draft regulation to incorporate the recommendations of the Advisory Committee; or

''(ii) publish an explanation of why the recommendation has not been adopted.

''(n) REPORT BY COMPTROLLER GENERAL.—Not later than 1 year after the date of enactment of this subsection, the Comptroller shall submit to the appropriate committees of Congress a report that—

''(1) describes the length of time required to complete the security checks and other procedures required for an institution to become a registered person;

''(2) makes recommendations on ways to reduce the length of time described in paragraph (1) without compromising security;

''(3) describes the ongoing costs for a registered person to comply with the requirements of regulations promulgated under this section;

''(4) makes recommendations on ways to reduce the costs described in paragraph (3) without compromising security; and

''(5) describes the degree to which registered persons that are nonprofit institutions are able to recoup the costs described in paragraph (3) from Federal agencies that provide financial support for research conducted at such institutions; and

''(6) describes the source or sources of funding used by registered persons that are nonprofit institutions to comply with the requirements of regulations promulgated under this section.

''(o) CLARIFICATION OF CERTAIN TERMS.—

''(1) FINDINGS.—Congress finds that—

''(A) certainty and predictability are essential for registered persons to be able to comply properly with the requirements of the regulations promulgated under this section;

"(B) the terms 'access' and 'incident' are of central importance in the requirements of such regulations; and

"(C) it is essential for there to be a clear definition in such regulations of such terms.

"(2) REQUIREMENT TO PUBLISH.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, the Secretary shall by regulation promulgate a definition of the terms 'access' and 'incident' as such terms are used in regulations promulgated pursuant to this section.

"(B) CONSULTATION.—In carrying out subparagraph (A), the Secretary shall consult with the Advisory Committee established under subsection (m) in the manner paragraph (3) of such subsection.".

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